

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Ulrike SCHULZ et al. Group Art Unit: 1616
Appln. No. : 10/574,219 Examiner: Karpinski, Luke E
I.A. Filed : April 27, 2005 Confirmation No.: 2157
For : AQUEOUS ANTI - PERSPIRATION FORMULATION

REPLY BRIEF UNDER 37 C.F.R. § 41.41(a)(1)

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window, Mail Stop Appeal Brief - Patents
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

This Reply Brief is in response to the Examiner's Answer mailed August 5, 2011, the period for reply extending until October 5, 2011.

In the Examiner's Answer all grounds of rejection set forth in the final rejection are maintained.

Appellants note that the Examiner's Answer does not sufficiently address several of Appellants' arguments as to why the rejections are without merit, and misrepresents some of the facts. These deficiencies have prompted the present Reply Brief.

Appellants also note that this Reply Brief is being filed under 37 C.F.R. § 41.41(a)(1) and is directed to the arguments presented in the Examiner's Answer, and therefore must be entered unless the final rejection is withdrawn in response to the instant Reply Brief.

In order to avoid repetition, the following response to the Examiner's arguments in the Examiner's Answer is limited to issues which are important enough to warrant a further comment in Appellants' opinion. Accordingly, Appellants' silence with respect to any

allegations set forth in the Examiner's Answer that are not specifically addressed below should by no means be construed as Appellants' admission that these allegations are of any merit.

REPLY

1. Appellants note that the Examiner appears to maintain the position that BANOWSKI et al., U.S. Patent No. 7,294,330 (hereafter "BANOWSKI") "teaches a finite and reasonable number of substances". In the paragraph bridging pages 16 and 17 of the Examiner's Answer the Examiner further alleges:

Further, when describing said substances, Bankowski et al. recite hydroxycarboxylic acids first and when describing aromatic carboxylic acids, Bankowski et al. recite mandelic acid first. While Bankowski et al. may mention a large number of beta-glucuronidase-inhibiting substances, ... only a fraction of said substances are specifically mentioned, including mandelic acid. It is therefore reasonable to state that when selecting a substance to start with, one would choose one of the specifically named substances.

Appellants submit that even if one were to agree, *arguendo*, with the Examiner that one of ordinary skill in the art would start with a substance that is *specifically* mentioned in BANKOWSKI, this "fraction" of beta-glucuronidase-inhibiting substances would be huge (far more than 100 compounds). For example, the beta-glucuronidase-inhibiting substances which are specifically mentioned in claims 2-10 and 13-16 of BANKOWSKI are as follows (emphasis added):

glycolic acid, lactic acid, α -hydroxybutyric acid, α -hydroxyvaleric acid and α -hydroxycaproic acid as well as physiologically acceptable salts thereof; gluconic acid, galactonic acid, mannonic acid, fructonic acid, arabinonic acid, xylonic acid, ribonic acid and glucoheptonic acid as well as physiologically acceptable salts

thereof; ascorbic acid, Na ascorbyl phosphate, Mg ascorbyl phosphate, ascorbyl palmitate, disodium ascorbyl phosphate, disodium ascorbyl sulfate, sodium ascorbate, magnesium ascorbate, ascorbyl stearate, ascorbyl dipalmitate, ascorbyl acetate, potassium ascorbyl tocopheryl phosphate, chitosan ascorbate and ascorbyl glucoside; methylglycinediacetic acid and its mono-, di- and tri-alkali metal salts, sulfosuccinic acid and its mono-, di- and tri-alkali metal salts; C₈-C₁₈-alkyl- (oligo)glucosylsulfosuccinic acid and its mono- and di-alkali metal salts; citric acid, malic acid (hydroxysuccinic acid), hydroxymaleic acid, hydroxyglutaric acid, hydroxyadipic acid, hydroxypimelic acid and hydroxyzelaic acid, C₈-C₁₈-alkyl (oligo-) glucoside esters thereof as well as the mono-, di- and tri-alkali metal salts and the aluminum salts of these components; erythraric acid (meso-tartaric acid), L-threarcic acid ((+)-tartaric acid), D(-)-tartaric acid, DL-tartaric acid, glucaric acid, galactaric acid (mucic acid), mannaric acid, fructaric acid, arabinaric acid, xylaric acid and ribaric acid, C₈-C₁₈-alkyl (oligo-)glucoside esters thereof as well as the mono-, di- and tri-alkali metal salts of these components; **mandelic acid**, parahydroxymandelic acid, rosemary acid, ferulic acid, chlorogenic acid, salicylic acid, 2,3-dihydroxybenzoic acid (pyrocatechic acid), 2,4-dihydroxybenzoic acid (β -resorcylic acid), 2,5-dihydroxybenzoic acid (gentisic acid), 2,6-dihydroxybenzoic acid (γ -resorcylic acid), 3,4-dihydroxybenzoic acid (protocatechuic acid), 3,5-dihydroxybenzoic acid (α -resorcylic acid), gallic acid, the methyl, ethyl isopropyl, propyl, butyl, hexyl, ethylhexyl, octyl, decyl, ethyloctyl, cetyl and stearyl esters and the alkali metal salts of these carboxylic acids; glycine, serine, tyrosine, threonine, cysteine, asparagine, glutamine, pyroglutamic acid, alanine, valine, leucine,

isoleucine, proline, tryptophan, phenylalanine, methionine, aspartic acid, glutamic acid, lysine, arginine and histidine as well as the zinc salts and the acid addition salts of the amino acids mentioned; naringin, α -glucosylrutin, α -glucosylmyricetin, α -glucosylisoquercetin, α -glucosylguercetin, hesperidin, neohesperidin, rutin, troxerutin, monoxerutin, diosmin, eriodictin, phloricin, neohesperidin dihydrochalcone and apigenin 7-glucoside; daidzein, genistein, glycitein, formononetin, daidzin and genistin; pyrocatechol, resorcinol, hydroquinone, phloroglucinol, pyrogallol, hexahydroxybenzene, anthocyanidines, flavones, tanning substances (catechols, tannins), usnic acid, acylpolyphenols as well as the derivatives of gallic acid, of digallic acid and of digalloylgallic acid; phenoxyethanol, 2-phenylethyl alcohol, 5-hydroxy-2-(hydroxymethyl)-4-pyrone (kojic acid), 5-methyl-2-(1-methylvinyl)-cyclohexan-1-ol (isopulegol) and 2-hydroxy-4-isopropyl-2,4,6-cycloheptatrien-1-one (hinokitiol).

Even the Examiner's assumed allegation that the first mentioned specific example of a particular type of beta-glucuronidase-inhibiting substances is the most preferred one is in contradiction to the fact that while mandelic acid is the first mentioned specific example of an aromatic carboxylic acid having 6-20 carbon atoms, 1-2 phenyl radicals, 1-6 hydroxyl groups and 1 carboxyl group, not mandelic acid but rosemary acid, ferulic acid and para-hydroxymandelic acid sodium salt are particularly preferred representatives of this group of compounds. See column 5, lines 7 and 8 of BANOWSKI.

2. In response to the argument that the instant claims recite an antiperspirant activated aluminum compound, i.e., not just an (any) antiperspirant aluminum compound (such as, e.g., aluminum chlorohydrate) and none of the (numerous) Examples of BANOWSKI illustrates the use of an activated aluminum compound the Examiner alleges at page 18, next-to-last paragraph of the Examiner's Answer that because BANOWSKI teaches activated aluminum compounds "one of ordinary skill in the art is well aware of the availability of activated aluminum antiperspirants and Bankowski et al. is not limited to the teachings of the examples."

In this regard, it is pointed out that the question here is not whether or not one of ordinary skill in the art is "is well aware of the availability of activated aluminum antiperspirants", but whether BANOWSKI prompts one of ordinary skill in the art to use an activated aluminum antiperspirant in combination with mandelic acid as beta-glucuronidase-inhibiting substance (in the ratios recited in the instant claims). In other words, the relevant question is "whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). Appellants further submit that in this regard it is necessary for the Examiner to properly construe what an applied reference *fairly* teaches or discloses. See, e.g., *In re Fracalossi and Wajer*, 681 F.2d 792 (CCPA 1982).

3. Appellants note that regarding the ratios of beta-glucuronidase-inhibiting substances and antiperspirants that can (theoretically) be derived from BANOWSKI the Examiner appears to be of the opinion that the fact that the corresponding ranges (or the overlapping part thereof) recited in the instant claims account for far less than 1 % of the

theoretical range derivable from BANOWSKI (based on preferred concentration ranges according to BANKOWSKI) and the fact that all of the ratios in the Examples of BANOWSKI which one might consider to be close enough to serve as at least some guidance in this regard are (far) outside the claimed ranges would be disregarded by one of ordinary skill in the art.

Appellants submit that there is an apparent discrepancy between the Examiner's apparent position that one of ordinary skill in the art would carefully go through the hundreds of beta-glucuronidase-inhibiting substances specifically mentioned in BANOWSKI and would allegedly choose mandelic acid because it is the first mentioned example of one particular (although not particularly preferred) type of hydroxycarboxylic acid (although mandelic acid is not among the most preferred examples and is not employed in any of the Examples of BANOWSKI) and the Examiner's apparent position with respect to ratio of antiperspirant and beta-glucuronidase-inhibiting substance, i.e., that one of ordinary skill in the art would allegedly not pay any attention to any guidance provided by BANOWSKI in this regard.

4. With respect to the rejection under 35 U.S.C. § 103(a) as allegedly being unpatentable over Shen, U.S. Patent No. 6,042,816 (hereafter "SHEN"), in view of Yu et al., U.S. Patent No. 5,571,841 (hereafter "YU") it appears that the Examiner is now taking the position that in view of YU one of ordinary skill in the art would employ mandelic acid in the compositions of SHEN in addition to the (most preferred) carboxylic acids taught by SHEN. See, e.g., page 21, first and third paragraphs and page 22, first paragraph of the Examiner's Answer. The alleged apparent reason for doing so would be

that YU teaches that “mandelic acid results in an increase in therapeutic effect of an active ingredient, including antiperspirants and that mandelic acid also treat[s] age spots, keratosis, and wrinkles.” On the other hand, the Examiner also alleges that based on the teachings of YU “one would reasonably expect ALL of the hydroxycarboxylic acids of YU [i.e., also the preferred hydroxycarboxylic acids of SHEN mentioned in YU] to achieve an enhanced therapeutic effect of an active”. Page 21, 5th paragraph of the Examiner’s Answer.

Appellants further are not aware that the treatment of age spots, keratosis, and wrinkles is considered to be a desirable (additional) feature of antiperspirants, and neither has the Examiner provided any evidence in this regard, although the Examiner takes the position that “[i]t is reasonable to state that an individual may very well be concerned with wrinkles in the armpits”. Page 22, 3rd paragraph of the Examiner’s Answer.

5. Regarding the foreseeable precipitation of the (only slightly soluble) calcium mandelate in the compositions of SHEN, the Examiner speculates that “if mandelic acid is added to the lower acid of Shen [as set forth above, the Examiner is now of the opinion that one of ordinary skill in the art would employ mandelic acid in addition to the acids recommended by SHEN] then the lower acid of Shen would have complexed with the calcium and there would be no calcium complex with mandelic acid to be able to precipitate” [thereby ignoring the basic rules of chemistry regarding the shifting of equilibria by precipitation]. Page 22, last paragraph of the Examiner’s Answer. The Examiner further asserts that “Shen et al. teach gel formulations which have much greater viscosities than aqueous solutions and salts generally do not precipitate out of gel

formulations”, again with out providing any evidence whatsoever to back up this assertion. Paragraph bridging pages 22 and 23 of the Examiner’s Answer.

At page 23 of the Examiner’s Answer the Examiner finally takes the position that “slightly soluble is still soluble” and that Appellants “cannot know with certainty what degree of soluble Shen meant to convey.”

In this regard, it is pointed out again that according to, e.g., claim 1 of SHEN a stabilized aqueous enhanced efficacy antiperspirant salt solution is to be formed. Further, according to col. 6, lines 37-41 of SHEN, “[g]enerally, the aqueous antiperspirant solution will contain about 0.3 to about 3% by weight Ca, preferably about 0.5 to about 2.5% by weight Ca, most preferably about 1.0 to about 2.0% by weight Ca, based on the weight of the entire composition”. It is apparent to one of ordinary skill in the art that these Ca concentrations cannot be obtained with a “slightly soluble” Ca salt.

CONCLUSION

The request to reverse the rejections of claims 46-48, 50-74, 76 and 77 and to return the instant application to the Examining Group for prompt allowance is respectfully maintained.

Although no fee is believed to be required for entry of this Reply Brief, the Patent and Trademark Office is hereby authorized to charge any fee that is deemed to be necessary to Deposit Account No. 19-0089.

Respectfully submitted,
Ulrike SCHULZ et al.

/Heribert F. Muensterer/

Heribert F. Muensterer, Ph.D.
Reg. No. 50,417

October 4, 2011
GREENBLUM & BERNSTEIN, P.L.C.
1950 Roland Clarke Place
Reston, VA 20191
(703) 716-1191